

REMARKS

The present final Office Action contains rejections of all of the pending claims under examination (i.e., Claims 44-68). More particularly, the Office Action contains both prior art-based rejections and non-prior art-based (i.e., formal) rejections of Claims 44-68. By the foregoing amendments, Claims 44-47 have been amended. The foregoing amendments and respective rejections are discussed below.

Claim Rejections - 35 USC § 112

Claims 44-68 were rejected under 35 USC §112, first paragraph, as failing to comply with "the written description requirement" thereof. By the foregoing amendment, independent Claim 44 has been amended to delete the text that the Examiner has rejected as constituting new matter (i.e., "such that said bone base and said cartilage cap are substantially free of cellular material"). Dependent Claims 45, 46 and 47 have also each been amended to replace the rejected language (i.e., "is substantially free of") with "has [or have] been treated to remove". In such circumstances, applicants' attorney respectfully submits that the 35 USC § 112, first paragraph rejections of Claims 44-68 have been overcome.

Applicants' attorney notes that the present final Office Action includes an introductory sentence relating to a claim rejection under 35 USC § 112, second paragraph, at the bottom of Page 3. However, no detailed rejection of any of the pending claims under 35 USC § 112, second paragraph, follows that introductory sentence. In such circumstances, applicants' attorney presumes that the inclusion of the 35 USC § 112, second paragraph sentence was an error, and that no response is required.

Claim Rejections - 35 USC § 103

Claims 44-68 were also rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,782,835 to Hart et al. ("the Hart et al. Patent") in view of (i) U.S. Patent No. 6,267,786 to Stone ("the Stone Patent"), (ii) an article by Peretti et al. ("the Peretti et al. article"), and (iii) an article by Hoffman ("the Hoffman article"). More particularly, the Examiner has taken the position that it would have been obvious to one skilled in the tissue engineering art to modify the cartilage repair implant of the Hart et al. Patent by using a method for producing "substantially non-immunogenic soft tissue xenografts" taught by the Stone Patent, such that the implant is "surrounded by a mixture of milled allograft cartilage pieces or mixture in a biocompatible polymeric carrier ..., as explicitly disclosed in the ... Peretti et al." article, with the Hoffman article disclosing "the use of various types of polymeric materials and hydrogels" as biocompatible carriers.

With respect to amended independent Claim 44, it recites a cartilage repair implant which includes an **allograft** plug (i.e., a graft of bone tissue from another individual of the same species as the recipient). In contrast to the allograft bone plug recited in independent Claim 44, the Hart Patent discloses an **autograft** bone plug (118) that is harvested from the patient him- or herself, and is subsequently implanted back into the patient's body. According to the specification of the Hart et al. Patent, during surgery, the autograft bone plug (118) is removed from a non-weight-bearing surface of the patient's joint (see col. 8, lines 36-49) and is then inserted into a bone hole (120) drilled into the bone at the site of a defect (110) in the patient's articular cartilage (112) (see col. 9, lines 26-54).

The Hart et al. Patent **neither discloses nor suggests** that the bone plug (118) may be an allograft, and therefore differs from the **allograft** plug of independent Claim 44.

Independent Claim 44 also recites that the allograft bone plug is **decellularized**. As conceded by the Examiner in the Office Action, the Hart et al. Patent **does not disclose** that the autograft bone plug (118) is decellularized. Any such decellularization treatment and/or processing of the autograft bone plug (118) would delay the immediate implantation of the autograft bone plug (118), and would have to be performed **separately** from the surgical procedure disclosed in the Hart et al. Patent, thereby complicating and delaying that surgical procedure and being contrary to the intended purpose of the Hart et al. Patent. Treating the autograft bone plug (118) as postulated by the Examiner would therefore defeat the purpose of the single surgical procedure disclosed in the Hart et al. Patent, and compromise any benefits obtained by performing such single surgical procedure. The Hart et al. Patent therefore **teaches away** from any modifications whereby the autograft bone plug (118) would be treated using the processes disclosed in the Stone Patent (i.e., subjecting the plug to a cellular disruption treatment and digesting the plug with a proteoglycan-depleting factor, and/or performing other processing steps thereon). For similar reasons, applicants' attorney respectfully submits that the Hart et al. Patent **teaches away** from performing **any** other treatment and/or processing steps (e.g., the processing steps of dependent Claims 45-47) on the autograft bone plug (118). For the foregoing reasons, applicants' attorney respectfully submits that one skilled in the tissue engineering art would **not** subject the fresh autograft Hart et al. Patent plug to the time-consuming processing steps disclosed in the Stone Patent.

Another improvement recited in independent Claim 44 is that an allograft milled cartilage mixture, which includes a biocompatible carrier, at least partially fills the space between the bore and a second sidewall portion of the decellularized plug to thereby enhance tissue integration between the decellularized plug and adjacent host tissue. The Examiner concedes in the Office Action that neither the Hart et al. Patent, the Stone Patent nor the postulated Hart et al./Stone Patent combination discloses a cartilage repair implant comprising an allograft milled cartilage mixture that includes a biocompatible carrier, as recited in Claim 44. The Examiner then asserts that it would have been obvious to one of ordinary skill in the tissue engineering art to modify the Examiner's postulated Hart et al./Stone Patent combination to include the cartilage mixture disclosed in the Peretti et al. article with a biocompatible carrier, as disclosed in the Hoffman article.

Even if the Peretti et al. article disclosed a cartilage mixture, and even if the Hoffman article disclosed a biocompatible carrier, applicants' attorney does not necessarily agree that it would have been obvious to combine them in a cartilage mixture, as postulated in the Office Action. Even if it were obvious to include the biocompatible carrier disclosed in the Hoffman article in the Peretti et al. article cartilage mixture, applicants' attorney respectfully submits that it would not have been obvious to a skilled artisan to use such cartilage mixture with the Examiner's postulated Hart et al./Stone Patent combination. Further, even if it were obvious to combine the Peretti et al. and Hoffman articles as combined by Examiner, such a combination would not render independent Claim 44 obvious because of the distinctions made above in connection with the Examiner's postulated Hart et al./Stone Patent combination.

In the foregoing circumstances, Applicants' attorney respectfully submits that the Hart et al. Patent, the Stone Patent, the Peretti et al. article and the Hoffman article, whether considered alone or in combination with each other, fail to anticipate and/or make obvious the cartilage repair implant recited in amended independent Claim 44. Because Claims 45-68 (including amended Claims 45-47) depend from Claim 44, they are believed to patentably distinguish over the aforementioned cited prior art references for the same reasons that Claim 44 does.

Provisional Double Patenting Rejection

The Office Action also contains a provisional nonstatutory obviousness-type double patenting rejection of Claims 44-68, based upon U.S. Patent Application Serial No. 10/438,883 ("the '883 Application"). Applicants' attorney respectfully submits that the facts explained below provide multiple bases for overcoming and/or obviating the present provisional double patenting rejection of Claims 44-68.

1. Inventorship and Ownership of the Present Application

All of the inventors named in the present application (i.e., Gordana Vunjak-Novakovic, Katherine G. Truncale, Moon Hae Sunwoo, Arthur A. Gertzman and William W. Tomford) have assigned their rights and interest in the application and invention to the Musculoskeletal Transplant Foundation ("MTF") except for Gordana Vunjak-Novakovic, who was employed by the Massachusetts Institute of Technology ("MIT") at the time of the invention. Dr. Vunjak-Novakovic, who no longer works for MIT, collaborated with Katherine G. Truncale, Moon Hae Sunwoo, Arthur A. Gertzman and William W. Tomford (hereinafter

"the MTF inventors"), but never assigned her rights and interest in the present application to MTF. In such circumstances, the present application is not owned exclusively by MTF (i.e., MTF is only a partial assignee of the present application).

2. Inventorship and Ownership of the '883 Application

The inventors in the '883 Application include only the aforementioned MTF inventors (i.e., Dr. Vunjak-Novakovic is not an inventor in the '883 Application). However, one of the MTF inventors (i.e., William W. Tomford) was not originally named as an inventor in the '883 Application. A Request to Correct Inventorship under 37 C.F.R. §1.48(a) was filed on February 12, 2009 in order to add William W. Tomford as a named inventor in the '883 Application. At this time, the Request to Correct Inventorship has not yet been considered by the Examiner in the '883 Application (i.e., Anuradha Ramana). However, if and when the inventorship of the '883 Application is corrected to name William W. Tomford as an inventor, both the inventorship and ownership of the '883 Application will still be different from that of the present application. For this reason, applicants' attorney respectfully submits that the provisional double patenting rejection of Claims 44-68 in the present application is improper.

3. Pending Claims of the '883 Application

Applicants' attorney notes that an Amendment was also filed in the '883 Application (hereinafter "the '883 Application Amendment") on February 12, 2009 in response to a Office Action dated November 12, 2008. The November 12, 2008 Office Action contained rejections of all of the pending claims of the '883 Application except for

Claims 45 and 49, which were indicated as being allowed. By the '883 Application Amendment, all of the claims of the '883 Application were canceled except for allowed Claims 45 and 49. Independent Claim 49 is set out below for reference:

A method of placing a preshaped allograft implant assembly in a cartilage defect, said assembly comprising a subchondral bone and an overlying cartilage cap plug which as been treated to remove cellular debris and proteoglycans and milled cartilage in a carrier comprising the steps of:

(a) cutting a first cylindrical bore in a patient at a site of a cartilage defect area to remove the cartilage defect;

(b) cutting a **second** cylindrical bore having a diameter greater than the first cylindrical bore a depth which is substantially the same as the depth of a cartilage layer in the defect area to form a **stepped bore**;

(c) placing a mixture of milled cartilage in a bioabsorbable carrier in the formed hole; and

(d) placing a preshaped allograft osteochondral plug having a cross section which engages the walls defining said hole allowing the structure to be placed in an interference fit within said stepped bore with the surface of the cartilage cap being substantially flush with surrounding cartilage.

Applicants' attorney notes that the provisional double patenting rejection of the present application is based on Claims 1-42 of the '883 Application. As explained above, Claims 1-42 of the '883 Application were canceled by the '883 Application

Amendment. Thus, applicants' attorney respectfully submits that the Examiner's basis for the provisional double patenting rejection of the present application has been eliminated.

Applicants' attorney also respectfully submits that neither independent Claim 49 nor its associated dependent Claim 45 of the '883 Application are valid bases for a double patenting rejection of the present application. More particularly, Claim 49 of the '883 Application recites a method including step (b), which calls for the formation of a "stepped bore", and step (d), which calls for the placement of the allograft osteochondral plug into the stepped bore. In contrast, none of the pending claims of the present application recite the formation of a stepped bore or the placement of the allograft bone plug therein. In such circumstances, applicants' attorney respectfully submits that allowed Claims 45 and 49 of the '883 Application are patentably distinct from the pending claims of the present application, and that a hypothetical further double patenting rejection of the present application based on those allowed claims would therefore be improper.

4. Prosecution of a Continuation Application

Applicants' attorney further notes that U.S. Patent Application Serial No. 12/179,034 was filed as a continuation of the '883 Application on July 25, 2008. The '034 Continuation Application, as filed, contains Claims 1-47, as copied from the '883 Application. However, applicants' attorney intends to cancel the presently pending claims of the '034 Continuation Application, and to add allowed Claims 45 and 49 from the '883 Application to the '034 Continuation Application. Applicants' attorney then intends to allow the '883 Application to go abandoned, and to prosecute the '034 Continuation Application instead. Applicants' attorney respectfully submits that once the '883 Application has been

abandoned, the basis for the Examiner's provisional double patenting rejection of the present application will be eliminated. Because the '034 Continuation Application will be amended to include allowed Claims 45 and 49 from the '883 Application, applicants' attorney respectfully submits that the '034 Continuation Application will not provide a basis for a new provisional double patenting rejection of the present application, for the reasons discussed above in connection with Claims 45 and 49 of the '883 Application.

It is respectfully submitted that the aforementioned double patenting rejection of Claims 44-68 has been obviated in light of the above discussion.

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Applicants also wish to inform the Examiner that U.S. Patent Application Serial No. 11/151,270 ("the '270 Application"), which was filed as a continuation-in-part of the '883 Application, issued as U.S. Patent No. 7,488,348 on February 10, 2009. The '270 Application was previously cited in the present application in an Information Disclosure Statement ("IDS") filed on March 20, 2008. The issued patent contains independent claims that were filed in the '270 Application subsequent to the filing of the March 20, 2008 IDS. Independent Claim 1 of the issued patent recites the combination of minced cartilage putty comprising milled cartilage pieces mixed in a biocompatible carrier and an allograft bone plug that includes a subchondral bone portion and an integral overlying cartilage cap which has been treated to remove cellular debris, chondrocytes and proteoglycans. The cap has a first cap portion located proximal to the subchondral bone portion with the same diameter, and a second cap portion located remote from the subchondral bone portion with a diameter

less than that of the subchondral bone portion. The first and second cap portions are separated by an annular step which forms a ring-shaped gap positionable alongside a cartilage layer exposed as a result of a bore formed in a defect area in articular cartilage of a host. The gap is sized and shaped so as to receive the minced cartilage putty therein. Independent Claim 18 of the issued patent recites a method for repairing an articular cartilage defect that utilizes the allograft bone plug and minced cartilage putty recited in independent Claim 1. The Examiner is invited to read the full text of the claims of the issued patent, which is attached hereto as an Exhibit for the Examiner's reference and convenience.

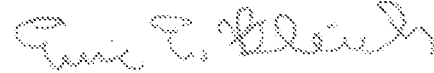
In view of the foregoing amendments and remarks, applicants' attorney respectfully submits that amended independent Claim 44 is directed to patentable subject matter and is in condition for allowance. Because Claims 45-68 (including amended Claims 45-47) depend from Claim 44, they are believed to be in condition for allowance for the same reasons that Claim 44 is allowable. Accordingly, applicants' attorney respectfully requests the reconsideration and allowance of Claims 44-68. If such action cannot be taken, the Examiner is cordially invited to place a telephone call to applicants' attorney in order that any outstanding issue may be resolved.

The accompanying Petition for a three-month extension of time authorizes the Examiner to charge the associated \$1,110 extension fee to Deposit Account No. 501561. The accompanying Request for Continued Examination of the present application authorizes the Examiner to charge the associated \$810 fee to Deposit Account No. 501561. If there are any additional fees due as a result of this Response, including extension and

petition fees, the Examiner is hereby authorized to charge them to Deposit Account No. 501561.

Respectfully Submitted,

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A handwritten signature in cursive script, appearing to read "Eric E. Bleich".

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